

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-154/S-029, S-030  
20-155/S-021  
20-156/S-022**

**PHARMACOLOGY REVIEW**

mammalian cell gene mutation assay; 3) the in vitro chromosomal aberrations assay in cultured human peripheral lymphocytes; 4) the in vitro chromosomal aberrations assay in Chinese Hamster Lung cells and 5) the BALB/c 3T3 in vitro transformation assay. No evidence of mutagenicity was observed in an Ames Salmonella bacterial mutagenicity assay or in rat and mouse micronucleus assays.

/S/

C. Anita H. Bigger, Ph.D.  
Pharmacologist

**Concurrences:**

HFD-530/WDemsey *CS* 8/16/99  
HFD-530/JFarrell 8/11/99  
HFD-530/ABigger *CS* 6-99

**APPEARS THIS WAY  
ON ORIGINAL**

**Disk:**

HFD-530/JFarrelly

**cc:**

- HFD-530 Original IND
- HFD-530 Division File
- HFD-340
- HFD-530/TCvetkovich
- HFD-530/RFleischer
- HFD-530/LMishra
- HFD-530/SMiller
- HFD-530/Biopharm
- HFD-530/ABigger
- HFD-530/DSullivan